protiviti®

Face the Future with Confidence

FMEA Audits — Why Do We Need Them?

Failure mode effects analysis (FMEA) is a valuable tool to evaluate a process, product or service that is being designed or redesigned, to help analyze potential failures within an existing process.

Companies often combine the requirements associated with FMEA with the International Organization for Standardization (ISO) to achieve quality control and address quality management in a manufacturing process.

Ideally, FMEA validates the safety and reliability of the manufacturing process while the ISO establishes the basic framework of quality management for the manufacturing unit. ISO audits are regularly scheduled internally (gap analysis, supplier or internal audits) or externally by ISO certifying or registrar entities (system or registration audits) to verify that the ISO management system is in compliance with the relevant standard. However, a FMEA audit is rarely seen on the audit schedule.

Empirical Ranking of a FMEA

An audit is critical to ensure the success of a productive FMEA. The FMEA may have underlying issues such as a lack of procedures, being incomplete, poor teaming and collaboration, or inadequate resources and documentation.

An empirical ranking-based audit approach can result in FMEA that can save money, increase productivity, enhance safety and provide improved manufacturing reliability.

Protiviti takes time to ensure your FMEA audit is tailored to your needs and the goals of the organization. Our exclusive ranking criteria have been developed by in-house experts who have evaluated FMEA across various organizations. Each of the 15 empirical elements incorporated into our FMEA audits provides valuable feedback across the organization and will set the basis for future FMEA.

FAILURE MODE EFFECTS ANALYSIS (FMEA) is also referred to as potential failure modes and effects analysis or failure modes, effects and criticality analysis (FMECA). The American Society for Quality (ASQ) defines FMEA as a step-by-step approach to identify all possible failures in a design, manufacturing or assembly process for a product or service.

FMEA Audit Elements

1. **Production Framework:** Evaluate the current manufacturing design and basis of FMEA.
2. **High Failure Nodes:** Identify all failure nodes with an effective mitigation plan.
3. **Process Evaluation:** Evaluate the plan in place that monitors identified failure modes
4. **Functionality:** Create a process map and analyze the FMEA process.
5. **Version Control:** Provide actionable steps from previous FMEA
6. **Tiering:** Review the established tier level for root causes
7. **Teaming and Collaboration:** Analyze adequate teaming and training
8. **Knowledge Base:** Retain the documentation and database.
9. **Implementation:** Design stages where FMEA can be applied
10. **Risk Mitigation:** Track and monitor risks identified in FMEA
11. **Monitoring:** Administer continuous periodic review of FMEA.
12. **Change Management:** Document process changes
13. **Integration:** Determine touch points of FMEA with Process Hazard Analysis (PHA) or ISO.
14. **Policies:** Establish corporate-level policies on maintaining FMEA
15. **Scoring Criteria:** Develop a simplistic 4-level or an exhaustive 10-level scoring system of criteria that can be based on the relevance of FMEA

FMEA is a powerful methodology for design and development teams to evaluate materials, components, processes and manufacturing. When combined with the proper ISO standard, your organization can complete a risk management process by identifying risks, hazards, severity and probability of occurrence, detection, and risk controls. Such a powerful resource warrants continuous audits to ensure future success.

Case Study

Protiviti evaluated FMEA and ISO for a composite materials manufacturer to identify the underlying cause of product quality issues. The audit revealed that even though the manufacturer maintained an active ISO certification, the FMEA was not current and was not updated per the corporate policy. Moreover, it was observed that the basis of design for the FMEA processes had changed significantly, as the manufacturer had made multiple changes to the manufacturing process over the years, but corresponding FMEA changes were not made to evaluate the impact on existing processes. Incomplete FMEA not only results in quality issues; it can also diminish teamwork and cross-functional working relationships within a manufacturing unit. In this particular case, the FMEA audit helped the manufacturer in redressal of quality issues that resulted in improved quality and reliability for manufacturing.

Contacts

Jon Critelli
+1.404.443.8218
jon.critelli@protiviti.com

Randall Coxworth
+1.312.476.6957
randall.coxworth@protiviti.com

Ruhtab Sahota
+1.713.314.1235
ruhtab.sahota@protiviti.com